



42187
C1-001

1220 L Street, Northwest
Washington, D.C. 20005-4070
Tel 202-682-8470
Fax 202-682-8031
E-mail baileyp@api.org

Paul Bailey, Director
Health and Environmental Affairs

44PP

April 4, 1997

OPPT Document Control Officer (7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Room G-099
401 M Street, S.W.
Washington, D.C. 20460

Contains No CBI

APR 10 1997
U.S. ENVIRONMENTAL PROTECTION AGENCY

Re: Proposed Test Rule for Hazardous Air Pollutants
[OPPTS-42187; FRL-4869-1; 61 FR 33177, June 26, 1996]

To Whom It May Concern,

The American Petroleum Institute (API) submits these comments on the Environmental Protection Agency's (EPA or "the Agency") proposed test rule (61 *Federal Register* 33177, June 26, 1996) under section 4(a) of the Toxics Substances Control Act (TSCA). This proposal would require manufacturers and processors of 21 hazardous air pollutants (HAPs) to test for certain health effects. API is a national trade association representing more than 300 member companies involved in all aspects of the oil and gas industry, including the major sectors of exploration, production, refining, transportation and distribution, and marketing of petroleum and petroleum products.

API's primary concern with this rulemaking deals with the status of petroleum streams and products. This long-standing precedent and Agency rationale reflected in prior TSCA section 4 test rules should hold true for this rulemaking also. Petroleum companies manufacture the streams listed on the TSCA inventory, but not the individual constituents that may be present in such streams. Therefore, only petroleum refiners that isolate regulated constituents from these streams are subject to this and other TSCA section 4 test rules.

APR 10 1997
U.S. ENVIRONMENTAL PROTECTION AGENCY



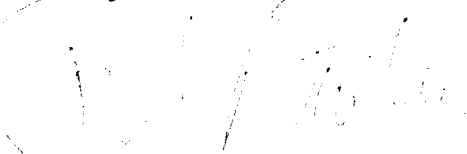
63970003544

OPPT Docket Clerk (7407)
Proposed Test Rule for
Hazardous Air Pollutants
April 4, 1997
Page 2 of 2

This issue and others are addressed in detail in our attached comments. API looks forward to meeting with the Agency to discuss these comments and provide any clarification regarding our concerns and recommendations.

If you have any questions regarding this letter or our attached comments please contact Walter L. McLeod of my staff at (202) 682-8493.

Sincerely,



Paul Bailey
Director, Health and Environmental Affairs

cc: Dr. Lynn Goldman, Assistant Administrator, OPPTS
Dr. William Sanders, Office Director, OPPT
Dr. Charles Auer, Division Director, CCD/OPPT
Dr. Ward Penberthy, Deputy Director, CCD/OPPT

682-8493
APR 11 1997
U.S. EPA
HEALTH AND ENVIRONMENTAL AFFAIRS

**Comments on the
Environmental Protection Agency's
Proposed Test Rule
for
21 Hazardous Air Pollutants (HAPs)**

**Proposed Test Rule
Solicitation of Comments
61 *Federal Register* 33177, June 26, 1996
[OPPTS-42187; FRL-4869-1]**

Prepared and Submitted by:

**American Petroleum Institute
1220 L Street, N.W.
Washington, D.C. 20005**

TABLE OF CONTENTS

I.	INTRODUCTION AND SUMMARY	1
II.	CHEMICAL SUBSTANCES AND PETROLEUM STREAMS.....	2
A.	PETROLEUM PROCESS STREAMS ARE “CHEMICAL SUBSTANCES”	3
B.	EPA HAS CONSISTENTLY APPLIED ITS PETROLEUM STREAM NOMENCLATURE TO IMPLEMENT TSCA REQUIREMENTS	5
1.	TSCA Section 4 Test Rules	5
2.	TSCA Section 8(a) Inventory Reporting	6
3.	TSCA Section 8(d) Health and Safety Study Reporting.....	7
III.	CARBONYL SULFIDE	8
A.	CARBONYL SULFIDE IS NOT WITHIN THE PURVIEW OF TSCA TESTING BECAUSE IT HAS NO COMMERCIAL MARKET	9
B.	THE USE OF TRI TO DEFINE AND IDENTIFY TSCA “MANUFACTURERS” IS PARTICULARLY ILL-ADVISED	12
IV.	SCOPE OF THE PROPOSED RULE	15
A.	EPA’S AUTHORITY TO SPECIFY TESTING UNDER TSCA SECTION 4 IS NOT UNLIMITED	15
B.	EPA’S BROAD TEST RULE WOULD REQUIRE FAR MORE TESTING THAN NEEDED TO IMPLEMENT CLEAN AIR ACT SECTION 112	17

TABLE OF CONTENTS (Cont'd)

V.	TESTING APPROACH AND SELECTION OF CHEMICAL SUBSTANCES	18
A.	A PHASED APPROACH IS WARRANTED.....	19
B.	EPA'S EMPHASIS ON "AN EVEN, ACROSS-THE-BOARD DATABASE" IS NOT JUSTIFIABLE FOR THIS DIVERSE SET OF COMPOUNDS	20
C	EPA'S SCREENING APPROACH IS INAPPROPRIATE.....	21
VI.	PROPOSED TESTING	22
A.	IMMUNOTOXICITY TESTING (EVEN AS A SCREENING TOOL) IS PREMATURE	28
B.	EPA SHOULD CONSIDER ALTERNATIVE TESTING PROPOSALS FOR LOW VAPOR PRESSURE COMPOUNDS.....	25
C	UNNECESSARY ACUTE TESTING.....	28
D.	UNNECESSARY RESTRICTIONS ARE IMPOSED ON THE USE OF ROUTE-TO-ROUTE EXTRAPOLATION.....	29
E.	THE AVAILABILITY OF LABORATORY CAPACITY MUST BE CONSIDERED WHEN ESTABLISHING COMPLIANCE DEADLINES	30
VII.	PROPOSED TESTING REGIME FOR CRESOLS, NAPHTHALENES, AND ETHYLBENZENE	32
A	CRESOLS.....	32
B.	NAPHTHALENE	34
C	ETHYLBENZENE	36

TABLE OF CONTENTS (Cont'd)

VIII. USES FOR TEST DATA.....	37
IX. CONCLUSION.....	38

**COMMENTS OF THE
AMERICAN PETROLEUM INSTITUTE
ON PROPOSED TEST RULE FOR HAZARDOUS AIR POLLUTANTS
61 FED. REG. 33178 (JUNE 26, 1996)**

I. INTRODUCTION AND SUMMARY

The American Petroleum Institute (API) submits these comments to the United States Environmental Protection Agency (EPA or "the Agency") on its proposed Toxic Substances Control Act (TSCA) section 4 test rule for hazardous air pollutants (HAPs). 61 Fed. Reg. 33178 (June 26, 1996). API is a national trade association representing more than 300 member companies involved in all aspects of the oil and gas industry, including exploration, production, refining, transportation, distribution and marketing of petroleum and petroleum products. Since a primary concern to API arising out of this rulemaking deals with the TSCA status of petroleum streams and products, we take this opportunity to reiterate that petroleum companies manufacture the streams listed on the TSCA Inventory, not the individual constituents that may be present in such streams. Accordingly and under the precedent of prior TSCA section 4 test rules and Agency interpretations, only those petroleum refiners that isolate regulated constituents (e.g., HAPs) from these streams are subject to this and other TSCA section 4 test rules.

Due to the variety of petroleum operations and the substances they manage, API has had a long-standing interest in EPA regulations and policy under TSCA. This test rule is of particular interest because of its scope and because it may set a precedent for future test rules. API offers comments on the approach, policies and requirements set forth in this proposal. Our comments include the following main points:

- EPA should require refiners to test only petroleum streams which are chemical substances listed on the TSCA Inventory.
- EPA should not use TSCA to require testing of substances for which there is no commercial market.

- EPA should not use TRI data to define and identify “manufacturers” of chemical substances under TSCA section 4.
- EPA required testing for HAPs should be tailored to address specific, identified data needs under Clean Air Act (CAA) section 112 mandates.
- EPA should adopt a tiered approach to testing and should focus on prioritizing data needed to assess the risks of specific chemicals rather than attempting to obtain a uniform, “across-the-board” data set.
- EPA should not use a screening approach based upon outdated TRI data and a poorly justified 50-ton screening criterion.
- EPA’s requirement for immunotoxicity testing is premature.
- EPA should focus on assuring that only information required under section 4 of TSCA is requested and used to promote responsible and effective risk assessment and communication.

API believes the proposed test rule raises a number of important issues that are central to the Agency’s continuing implementation of TSCA section 4. We look forward to working with EPA to address these issues.

II. CHEMICAL SUBSTANCES AND PETROLEUM STREAMS

Petroleum companies are TSCA manufacturers of the “chemical substances” that are identified and listed on the TSCA Inventory as petroleum process streams - not the individual constituents of these separately defined chemical streams/substances. These companies “manufacture” stream constituents as chemical substances subject to testing only when they are isolated for subsequent sale or later addition to another petroleum process stream (e.g., if a stream constituent is isolated, it then becomes a separate chemical substance subject to appropriate TSCA regulation, including testing). This rulemaking includes several chemicals that may be present in petroleum process streams and included in their inventory listing descriptions. Consistent with prior Agency interpretations and past practice, petroleum

companies should be subject to this rule only if they isolate these HAP constituents as separate chemical substances. The Agency should reaffirm this approach when finalizing these rules.

A. Petroleum Process Streams are “Chemical Substances”

Crude oils are highly variable, complex combinations of literally thousands of naturally occurring substances, hydrocarbon compounds and other materials. At its most simplistic level, the process of refining crude oil into petroleum products involves separating these materials and hydrocarbon compounds into several streams which are complex chemical substances, largely based on their boiling ranges (resulting in products within particular carbon number ranges), minimizing the presence of unwanted contaminants and impurities, and transforming less valuable hydrocarbon stream constituents into higher value compounds. Typical refinery processes begin with distillation (atmospheric and vacuum), followed by some or all of the following: catalytic cracking; catalytic reforming; alkylation; polymerization; isomerization; hydrocracking; thermal cracking; sweetening, sorption; solvent refining; acid treating; chemical neutralization; clay treating; hydrotreating; dewaxing; and hydrodesulphurization. Early in the development of TSCA, API worked closely with the Agency to identify and define the streams from each of these processing operations as individual “chemical substances.” This collaborative effort resulted in the TSCA Inventory defining and identifying petroleum process streams as individual “chemical substances.” This carefully constructed, systematic and comprehensive approach and nomenclature necessarily controls all aspects of oil industry compliance with TSCA provisions applicable to chemical substances, including testing obligations under TSCA section 4.

Each manufacturing unit within a refinery produces one or more petroleum process streams that appear on the TSCA Inventory as separate chemical substances. For example, the following chemical substances/streams are listed as being produced by a fluidized catalytic cracker (FCC):

<u>Chemical Substance</u>	<u>CAS #</u>
• <i>Naphtha (petroleum), heavy catalytic cracked</i>	(64741-54-4)
• <i>Naphtha (petroleum), light catalytic cracked</i>	(64741-55-5)
• <i>Distillates (petroleum), light catalytic cracked</i>	(64741-59-9)
• <i>Distillates (petroleum), intermediate catalytic cracked</i>	(64741-60-2)
• <i>Distillates (petroleum), heavy catalytic cracked</i>	(64741-61-3)
• <i>Clarified oils (petroleum), catalytic cracked</i>	(64741-62-4)

Chemical substances are described on the TSCA Inventory by their boiling ranges and carbon number ranges to capture the wide range of individual chemicals present. Some of the HAP constituents like naphthalene and biphenyl may be naturally present in feedstocks to the FCC, and also generated in the FCC along with other hydrocarbons.

Petroleum companies use this process stream nomenclature for identifying the streams/chemical substances they produce, for complying with TSCA section 8(d) and for specifying the volumes of such streams/chemical substances manufactured, as required by periodic reporting requirements under the TSCA Inventory Update Rule, 40 CFR 710.32(c)(7). As noted, petroleum refiners produce defined streams that are composed of numerous, highly variable hydrocarbon constituents. For example, cresols and phenols (in essence, toluene alcohol and benzene alcohol) are naturally occurring in crude oil and may also be generated in processing units.

As the foregoing discussion demonstrates, the full suite of hydrocarbons processed and/or produced at a refinery are subsumed within multiple “chemical substance” definitions as being manufactured by a petroleum refinery (i.e., identified and listed petroleum process streams). Refineries do not produce the individual hydrocarbons that are the subject of this rulemaking (i.e., ethylbenzene, naphthalene and biphenyl)¹.

¹ Some refiners isolate/extract these constituent components for sale or later use as part of their petrochemical operations and, as such, would be subject to this rule as “manufacturers of that component chemical substance.”

B. EPA has consistently applied its petroleum stream nomenclature to implement TSCA requirements.

The oil industry has been consistent in its view that it produces the individual streams defined and included by EPA in its list of chemical substances manufactured and processed in the United States - not the constituents of such streams. This view, long maintained by the industry, has also been recognized by the Agency in prior TSCA section 4 test rules² and in its implementation of TSCA section 8.

1. TSCA Section 4 Test Rules

Most recently, EPA corrected an important misstatement contained in the Office of Water Chemicals Final Test Rule, 58 Fed. Reg. 59667 (November 10, 1993). The Agency initially opined that manufacturers of the C9 aromatic hydrocarbon stream listed on the TSCA Inventory were responsible for testing 1,3,5-trimethylbenzene (TMB), one of several isomers present in the C9 stream. In a subsequent clarification to the final rule, EPA stated:

In summary, for persons who manufacture, import, and process TMB as an isolated product, the test rule is valid and applicable to them. EPA is now clarifying that persons, including relevant petroleum refiners, who do not manufacture, import, or process TMB as an isolated product are not required to submit test data, letters of intent to test, applications for exemptions, import certifications, or any other item that may be required pursuant to a final test rule under TSCA section 4.

² API and its member companies raised this streams/constituents issue on at least three occasions in the context of EPA's TSCA section 4 program: C9 aromatic hydrocarbons, 48 Fed. Reg. 23088 (May 23, 1983); commercial hexane, 51 Fed. Reg. 17854 (May 15, 1986); and cresols, 48 Fed. Reg. 31812 (July 11, 1983).

59 Fed. Reg. 45629 (September 2, 1994). This clarification is in harmony with the prior test rule on the C9 aromatic hydrocarbon stream, which required that refiners test the C9 stream, not individual constituents of that stream (isomers of methylethylbenzene and trimethylbenzene), as originally proposed. 50 Fed. Reg. 20662 (May 17, 1985).

EPA followed the same pattern when it proposed to require testing of commercial hexane and methylcyclopentane (MCP), a substantial component of commercial hexane. 51 Fed. Reg. 17854 (May 15, 1986). In the final rule, however, EPA declined to require MCP testing because it “. . . is currently not isolated. . . , is not manufactured for direct sales. . . [and] its production as a discrete substance has not been reported on the TSCA Inventory Update Rule. . .” 53 Fed. Reg. 3382, 3386 (Feb. 5, 1988). Similarly, petroleum refiners were not required to test cresols, found in trace amounts in some petroleum streams; only those companies that manufactured cresols as independent products for sale were required to so test. 51 Fed. Reg. 15772 (April 28, 1986).

Thus, EPA has consistently required refiners to test only petroleum streams that are on the TSCA Inventory as individual chemical substances, not the constituents of such streams. This approach also conforms with the approach EPA has taken under TSCA section 8.

2. TSCA section 8(a) Inventory Reporting

EPA’s approach to the reporting of petroleum streams on the TSCA Inventory is well summarized in its amendments to the Preliminary Assessment Information Rule, 49 Fed. Reg. 25857 (June 25, 1984). In its analysis of comments on this rule, EPA stated that: “reporting is not required on chemicals which are not marketed for commercial sale as section 8(a) subject chemicals but simply are part of a larger product stream.” 49 Fed. Reg. 25857 and 25858.

3. TSCA section 8(d) Health and Safety Study Reporting

TSCA section 8(d), like section 4, applies to manufacturers and processors of listed “chemical substances.” 40 CFR 716.5. Manufacturers of a chemical substance listed as a “byproduct” , “impurity” or as the pure chemical are required to review their files and submit/list health and safety studies on that chemical substance to EPA, including studies of mixtures known to contain that chemical substance. 40 CFR 716.20(a)(2). To avoid confusion and clarify the applicability of these requirements to particular situations, the Agency periodically issues questions and answers to aid the regulated community in complying with the Act. As to petroleum refining operations, EPA significantly clarified the TSCA status of petroleum process streams when it was asked whether studies on petroleum had to be submitted simply because they contained 8(d) listed chemicals as natural components:

EPA Answer

No. For purposes of reporting under the section 8(d) rule, studies on refinery streams will not have to be submitted if natural components of the stream are subject to the section 8(d) rule. For instance, companies would not have to submit studies on petroleum, which contains toluene a listed section 8(d) substance. However, if a company separately produces toluene, then any health and safety studies on toluene must be submitted. Many refinery streams are listed on the TSCA Inventory as chemical substances. Studies on a stream would be submitted only if the stream becomes subject to section 8(d).

General Questions and Answers About Reporting Under the TSCA Sec. 8(d) Health and Safety Study Reporting Rule (revised, February 16, 1989). Since the scope of the TSCA section 8(d) model rule is identical to the scope of the testing program under TSCA section 4 and since TSCA section 8(d) aids and informs the formulation of testing decisions under section 4, it necessarily

follows that these questions and answers should be dispositive here. Simply put, the petroleum industry is responsible for testing defined process streams - not the individual hydrocarbon constituents that may be contained in these streams³.

To summarize, the Agency has not previously required testing of stream constituents under its TSCA section 4 program. Rather and consistent with its TSCA section 8(a) Inventory reporting requirements and its TSCA section 8(d) Q & As, it has required testing only of constituents that have been isolated⁴. We urge EPA to retain its current approach and require testing by only those refiners that isolate component constituents from their processing streams/chemical substances⁵.

III. CARBONYL SULFIDE

As stated in EPA's "Section 4 Test Rule Support for 21 Hazardous Air Pollutants," April 4, 1995, ("Support Document"), carbonyl sulfide is the most abundant sulfur-bearing compound in the atmosphere. Support Document at 2 and 4. According to EPA, it is believed to originate from microbes, volcanoes, the burning of vegetation and some industrial processes. *Id.* Moreover, carbonyl sulfide lacks any full-scale production in the United States. *Id.* Since it is not produced in large quantities by man, has no commercial market and originates largely from uncontrollable natural sources, we believe carbonyl sulfide presents a particularly unique case. We urge the Agency not to contort the language of the statute or misconstrue underlying Congressional intent when enacting TSCA by requiring testing of carbonyl sulfide under TSCA section 4. Moreover, we argue that the use of the Emergency Planning and Community Right-

³ API recently reiterated this view in its comments to the Agency on its contemplated regulatory changes to TSCA 8(d) program. Comments of the American Petroleum Institute on Review of Reporting Requirements under TSCA Section 8(d) (Nov. 1, 1996).

⁴ See 59 Fed. Reg. 45629 (Sept. 2, 1994)(TMB) and 53 Fed. Reg. 3382, 3386 (Feb. 5, 1988)(MCP and commercial hexane final rule).

⁵ For example, if a refinery isolates ethylbenzene from its heavy catalytic cracked naphtha stream (64741-54-4) for subsequent sale or later addition to another stream elsewhere in the refining process (e.g., as an octane enhancer in finished gasoline), it would then be a manufacturer of ethylbenzene and, as such, subject to the rule.

to-Know Act Toxic Reporting Inventory (EPCRA/TRI) submissions to identify TSCA manufacturers is ill-considered because of the limitations inherent in these submissions, the fundamentally different objectives served by EPCRA and TSCA (discussed in Section B of these comments, supra), and the specter of significant, potentially unintended consequences occurring here and under other past and future test rules.

A. Carbonyl sulfide is not within the purview of TSCA testing because it has no commercial market.

EPA recognizes that carbonyl sulfide represents its first attempt to subject a chemical substance to testing that is produced almost exclusively as a waste byproduct or byproduct impurity. 61 Fed. Reg. at 33190. Indeed and as identified in reports supporting this rulemaking, there is no identifiable market for carbonyl sulfide and no commercial use under TSCA for this substance:

Since no US full-scale commercial production is known to exist, no production data of any kind (i.e., CBI or non-CBI) is available. No trade statistics are available.

Furthermore, no sales price data is available for bulk quantities. Therefore, since no actual supply volume or sales price data is obtainable, an estimate of these respective values required to support testing at the one percent of price impact level [as required by EPA guidance] is difficult to derive.

* * * * *

With the currently available data, no conclusion is possible regarding the likelihood or degree of adverse economic impact of testing on the producers of carbonyl sulfide.

Section 4 Test Rule Support for 21 Hazardous Air Pollutants, Mathtech, Inc. (revised draft, April 4, 1995) at pp. 49-50. This substance is clearly not of the type envisioned by Congress when enacting TSCA section 4.

The structure of the Act contemplated that all existing chemical substances manufactured or processed in the United States would be identified in the TSCA Inventory and that manufacturers and processors of these substances would identify themselves and provide required information to EPA [TSCA sections 8(a) and (b)]. Thereafter, new chemical substances would first go through a premanufacture notification process and then be added to the Inventory, subjecting them to applicable reporting and recordkeeping obligations [TSCA section 5]. Manufacturers and processors maintain records of allegations of significant adverse reactions to their chemicals [TSCA section 8(c)], submit health and safety studies of them to EPA [TSCA section 8(d)], and notify the Administrator of substantial risk information concerning these chemical substances [TSCA section 8(e)]. These several sources inform the Agency and typically constitute the basis for its requiring testing under TSCA section 4 and/or regulating these substances under TSCA section 4.

Implicit throughout the Act and its legislative history is a recognition that covered chemical substances are marketed and that their manufacturers thereby obtain some direct economic benefit from the production of the substances. In explaining the purpose of the legislation which later became TSCA, the House Commerce Committee stated:

[T]hrough its testing and premarket notification provisions, the bill provides for the evaluation of the hazard-causing potential of new chemicals before *commercial production* begins. . . Further, manufacturers and processors of potentially hazardous *chemicals already on the market* may be required to test them to determine their effects on health and the environment. . . In addition, the bill provides for the collection of

information regarding *commercially produced* chemicals so that the total exposure to a chemical and its total effect on health and the environment can be monitored and evaluated.

(emphasis added) H.R. Rep. No. 1341, 94th Cong., 2d Sess. (1976) at pp. 1-2.

When discussing the definition of “chemical substance,” the House Senate Conferees also stated that this term “shall be applied to chemical substances as actually produced and marketed,” H.R. Rep. at 57. *See also* TSCA section 2(a)(2) and (b)(1). Similarly and when discussing how the Agency is to determine what constitutes a fair and equitable reimbursement for tests performed by others under TSCA section 4, the Act specifies that EPA is to consult with the Attorney General and the Federal Trade Commission and to consider the parties’ relative competitive positions and their market shares for the substance to be tested, along with other relevant factors. TSCA section 4(c)(3)(A). These requirements clearly contemplate a commercial market for the chemical substances to be tested. If they did not, there would have been no point in identifying trade, antitrust and market share considerations in the statute. On the other hand, refinery streams are commercial in nature, and therefore an interpretation of TSCA defining petroleum refinery streams as “chemical substances” is easily harmonized with Congressional intent.

Carbonyl sulfide is a natural occurring constituent in some crude oils (e.g., heavy sour crudes). Through the refining process and to comply with applicable regulatory restrictions on fuels, efforts are made to convert sulfur containing compounds to hydrogen sulfide plus hydrocarbon and then separate them from the process/product streams. When separated, the hydrogen sulfide is typically directed to a sulfur plant⁶ where the hydrogen sulfide is then managed in sulfur recovery units; carbonyl sulfide may also be formed as a byproduct/impurity in these units. To comply with EPA-mandated sulfur dioxide emission requirements in [some]

⁶ Although these plants produce elemental sulfur for sale, they are not economic in and of themselves (i.e., they are not “profitable” since their total costs of operation typically exceed revenues).

SO₂ nonattainment areas, these units must have control devices (e.g., tailgas units). It is from these regulatorily mandated tailgas units that carbonyl sulfide at extremely low levels (e.g., 3 - 30 ppm) is emitted to the atmosphere⁷.

Sound legal construction and good public policy suggest that where there is no commercial market anywhere for a substance, where the only “benefit” derived by its producers is several steps removed from any potential economic advantage or commercial product, and where that substance is only produced unintentionally by virtue of a process required by law, its producers should not then be responsible for testing under TSCA. Testing for carbonyl sulfide is the second most expansive and expensive (\$5,509,163) under this proposal. The fact that relatively little information on carbonyl sulfide has been developed should come as no surprise because there are no “true” manufacturers of this chemical. Since EPA is to carry out its responsibilities under the Act “in a reasonable and prudent manner,” TSCA section 2(c), logic, common sense and good public policy, reflected largely in the structure and goals of the Act, argue forcefully for the Agency not to require testing of carbonyl sulfide under TSCA section 4.

B. The use of TRI to define and identify TSCA “manufacturers” is particularly ill-advised.

In this proposal EPA equates TSCA “manufacture” with release reporting under EPCRA’s section 313 toxics release inventory (TRI). This approach would fundamentally alter the scope of TSCA and the regulated community’s compliance obligations. For example, if reported TRI releases are equated with TSCA manufacture, the Agency might next suggest

⁷ The Interagency Testing Committee (ITC) earlier concluded that testing is not needed for carbonyl sulfide, primarily because of the insignificant exposure potential from facility emissions, and also based on a comparison of exposures from manufacturing process emissions with emissions from natural sources of carbonyl sulfide. See Comments of CMA on Proposed Carbonyl Sulfide Section 4 Test Rule, Attachment 1 (ITC Statement), December 6, 1994. Although the refining industry has not been singled out or is a particular target of this proceeding, we note that only three refineries submitted 1993 TRI reports for carbonyl sulfide, collectively reporting a total release of only 111,000 pounds (out of the 16,700,000 pounds reported as released that year), or less than 0.7% of total releases.

identifying offsite waste transfers and on-site waste treatment, also identified in TRI submissions, as constituting TSCA “manufacture.” This underscores the need for EPA to abandon its proposed linkage of TSCA with data and information generated under TRI/EPCRA, an entirely different statute with substantially different purposes implemented through a significantly different regulatory regime⁸.

EPCRA/TRI release reporting applies to “any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment.” EPCRA section 329(8). As such, its focus is largely upon wastes, whereas TSCA focuses on commercial chemical substances. Moreover, the concept of “EPCRA manufacture” is markedly different from “TSCA manufacture.” Transitory chemicals produced for as little as a picosecond in a reactor are considered to be incidentally manufactured for EPCRA purposes and counted towards TRI reporting thresholds. Since the purpose of EPCRA/TRI is to inform the public, this approach makes sense to the extent such transitory chemicals may be released as wastes and enter the community. TSCA, however, excludes such chemicals, an approach that also makes sense because transitory chemicals are neither commercially marketed nor manufactured for commercial purposes.

In identifying manufacturers and assessing whether the imposition of testing obligations would cause an unfairly adverse economic impact, EPA typically relies upon commercial data (e.g., the Chemical Marketing Reporter, the Directory of Chemical Producers and International Trade Commission reports on synthetic organic chemical production and sales). This is to be contrasted with TRI submissions that are commonly based upon best estimates of volumes produced and quantities released. In addition, EPA recognizes several justified exemptions from TRI reporting, 40 CFR 372.38 (*no* comparable exemptions are recognized under TSCA). More importantly, EPCRA specifies TRI reporting thresholds of 25,000 pounds per year for

⁸ For example and under this approach, facilities that had reported releases of previously tested chemicals but that did not then test or pay for such testing could be placed in enforcement jeopardy and exposed to retroactive liabilities to those who had tested these substances.

manufacturers (*no* thresholds exist under TSCA) and minimum ten person manning requirements (*no* small business exemption is found in TSCA section 4). Collectively, these several distinctions render TRI data to be a particularly inappropriate tool for identifying covered parties and imposing testing obligations under TSCA.

An added, practical complication arises out of the TSCA use of TRI information submitted by refineries. The refining industry has generally not applied TSCA nomenclature (i.e., petroleum refinery process streams/ chemical substances) in fulfilling EPCRA obligations, including TRI reporting⁹. Although the definitions under EPCRA and TSCA are similar, they are not the same. *Compare* 40 CFR 372.3 *with* 40 CFR 704.3. For example, there is no requirement under EPCRA, as there is under TSCA, that manufacturing be conducted with commercial intent.

It is entirely possible for a refiner to manufacture an identified EPCRA toxic chemical for TRI reporting but not be a TSCA manufacturer of that constituent. For example, if a refinery spills a processing stream containing ethylbenzene, it might well work backward to identify whether it is an EPCRA manufacturer of ethylbenzene. Thus, even if ethylbenzene is present as a constituent of a TSCA “chemical substance” (i.e., a defined and listed petroleum process stream), a refiner would likely consider it to be an EPCRA byproduct and/or processed for on-site use (e.g., as part of a stream that is processed further) and/or sold (e.g., as part of a stream that is combined with other streams and sold as a finished product, either with or without intermediate processing). Thus, relying upon TRI data as a basis for imposing TSCA requirements could be misleading and permit the drawing of erroneous conclusions as to manufacture.

Clearly, these disconnects between TRI data under EPCRA and the commercial information needed to implement TSCA, stand to highlight the remarkably poor fit of the two statutes in this proposed rule. We recognize that the Agency may feel compelled to utilize

⁹ As discussed above, petroleum process streams are TSCA “chemical substances”, but this key concept has no corollary under EPCRA. For TRI reporting, one necessarily considers speciated listed chemicals.

EPCRA/TRI data because there is simply *no* market information or price data for carbonyl sulfide on which to base its actions under TSCA section 4. Rather than contorting logic and creating a precedent of yet-to-be-defined dimensions to address an admittedly unique case, we urge the Agency not to require TSCA testing of carbonyl sulfide. Even if testing is required, EPA should not equate reporting of a substance on the EPCRA TRI with the “manufacture” of such substance for TSCA purposes.

IV. SCOPE OF THE PROPOSED RULE

A. EPA’s authority to specify testing under TSCA section 4 is not unlimited.

The proposal states that once the Agency has made the requisite findings under TSCA section 4, it may require any type of testing it deems necessary to address unanswered questions about the effects of a chemical substance. 61 Fed. Reg. at 33179. It goes on to state that the scope of testing is not limited by the factual basis of the findings, that it need not limit testing only to that which may be necessary to support regulatory action under TSCA, and that it may utilize TSCA to obtain whatever data it chooses to support implementation of other statutory programs (i.e., CAA section 112). *Id.* Although we do not concede it, neither do we here question EPA’s authority to use TSCA to obtain information for other regulatory programs. Rather, we submit that when EPA requires testing under TSCA section 4 to support such other programs, the scope of testing must be limited to that which is required under the statute authorizing such other program. If it is not, TSCA section 4 could be read as giving the Agency a roving commission to require any type or level of testing without meaningful limitations.

The language of the statute makes clear that Congress intended EPA to: (1) focus on health and environmental effects for which there are insufficient data; and (2) concentrate on collecting data that are relevant to specific determinations. API believes that EPA has exceeded

its authority to develop data “relevant to a determination that [an activity]. . . or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.” TSCA section 4(a). As with any other action under TSCA section 4, the scope of testing must be limited to developing data “relevant to a determination” which, in this case, is a residual risk determination under CAA section 112.

Instead of focusing on collecting specific data for an identified need (e.g., a residual risk determination), “EPA is proposing to obtain an even, across-the-board database” for the subject chemicals. 61 Fed. Reg. at 33181. EPA's primary purpose for collecting this data is to implement section 112 of the Clean Air Act, but the extensive testing that EPA has proposed goes far beyond what is needed to satisfy CAA section 112 mandates. EPA tacitly acknowledges this by its preamble emphasis on “secondary—though as important—uses of the data.” 61 Fed. Reg. at 33180. While other agencies may have other uses for the data, the same could be said of almost any testing data that the Agency might choose to collect—especially a data set as broad as the one EPA would require under this rule. Desire or interest by others simply is not the same as Agency need or necessity.

The present rulemaking essentially identifies a very generalized data need (to comply with CAA mandates), promulgates overbroad testing requirements (going far beyond that which may be necessary to comply with CAA mandates) and then justifies these requirements by listing other, possible uses/users of the data. This cast-a-broad-net approach is simply not good public policy; more should be and is required. To comply with Congressional intent, comport with common sense and fulfill its statutory mandate, EPA must first articulate a clear need for certain identified data, link that need to an unreasonable risk determination, and then specify precisely how a particular test will fill that need and facilitate that determination.

B. EPA's broad testing rule would require far more testing than needed to implement CAA section 112.

EPA states that data generated by the proposal will be used in analyses to determine the nature and magnitude of residual risk and whether health-based, post-MACT standards are needed to provide an “ample margin of safety to protect public health” and to ensure that excess cancer risk is less than one in a million. CAA section 112(f)(2)(A). API submits that there is a considerable mismatch between (1) the information realistically needed to calculate residual risk for these identified HAPs and (2) the broad set of information to be developed under this proposal¹⁰. Key mismatches include:

- Since risk is a function of both potential health effect and exposure, EPA will not need broad-based health effects information for those HAPs where exposure is minimal or will be reduced to minimal levels by MACT standards. It will likely be the case, at least for some, that existing toxicity data and air dispersion modeling will suffice for evaluating residual risk (e.g., to demonstrate that reasonably anticipated emissions following installation of engineering controls will not pose significant hazards to human health).
- EPA quotes a National Academy of Sciences (NAS) finding that data availability varies widely among the 189 HAPs. 61 Fed. Reg. at 33181. In addition, EPA's Office of Research and Development has documented considerable variation in the available data for HAPs, and that “fair or better” health effects data are available for two of the HAPs subject to the proposed test rule.¹¹ Given the wide variation in available data, EPA should focus on filling critical gaps for the

¹⁰ The policy issue here is of particular concern because EPA has indicated that at least 29 additional HAPs are under active consideration for future TSCA section 4 test rules. 61 Fed. Reg. at 33184.

¹¹ U.S. EPA Office of Research and Development, *EPA's Urban Area Source Research Program: A Status Report on Preliminary Research*, February, 1995, EPA/600/R-95/027, at pp. 44-53.

purposes of risk assessment rather than imposing broad, “across-the-board” testing requirements. This point is especially important in the area of acute toxicity testing. As the Chemical Manufacturers Association has already indicated, many of the chemicals subject to this proposed rule have been extensively tested for acute effects and do not warrant the acute testing EPA is proposing¹².

- EPA reasons that the large number of HAPs of concern and the much larger combinations of those HAPs found in the mixtures of emissions subject to residual risk evaluation warrant obtaining an “even, across-the-board database.” 61 Fed. Reg. at 33181. API believes the reverse to be true: the large number of HAPs and complex combinations of HAPs in mixtures warrant careful targeting and a step-wise approach to testing, (*see* discussion below).
- EPA's soon-to-be-issued report to Congress will describe its methodology for assessing residual risk in the post-MACT world. This place-the-cart-before-the-horse approach is disconcerting (e.g., EPA is requiring testing to develop data to support decision making before it articulates what decisions it will make or on what basis it will make them).

V. TESTING APPROACH AND SELECTION OF CHEMICAL SUBSTANCES

Although this proposal does not generally apply to refineries, it raises several extremely important issues that transcend particular chemicals of concern to the petroleum industry. API is concerned that without adequate justification, EPA has ignored the recommendations of NAS that EPA use a phased approach and develop incentives to encourage the development of needed data by other public agencies, rather than industry. Similarly, API objects to EPA's “across-the-

¹² “Preliminary Comments on EPA's Proposed Test Rule for Hazardous Air Pollutants,” submitted by Chemical Manufacturers Association, September 24, 1996.

board database” approach as, given the physical and chemical diversity of the 21 compounds involved, it is inappropriate to require the same testing for each chemical. Finally, API believes that EPA’s screening approach is faulty because, among other reasons, it does not consider post-MACT emissions or evaluate whether there is significant potential for exposure to air releases of the HAP chemicals.

A. A phased approach is warranted.

EPA quotes the NAS recommendation that “[EPA] screen the 189 chemicals for priorities for the assessment of health risks, identify the data gaps, and develop incentives to expedite generation of the needed data by other public agencies... and by other organizations...” 61 Fed. Reg. at 33183. EPA states that it has taken this approach, but its assertion is belied by the Agency’s calling on the regulated community to generate an “even database covering HAPs across the same broad set of endpoints.” 61 Fed. Reg. at 33183. The NAS recommended an iterative testing approach to the generation of health effects data on HAPs. 61 Fed. Reg. at 33183. NAS also recommended that HAPs be prioritized on the basis of acute toxicity and chemical structure and that testing might proceed stepwise, on a case-by-case basis from acute toxicity to studies of the uptake, distribution, retention, and excretion of the substance, to subchronic toxicity and ultimately, if needed, to endpoint testing in animals - only then would EPA decide if further studies of human toxicity or mechanisms are warranted.

EPA's stated rationale for rejecting the NAS approach is that an iterative testing approach “would be time consuming”, “require multiple rulemakings” and “take too long to collect useful data for making decisions needed to meet upcoming statutory deadlines established in the CAA.” 61 Fed. Reg. at 33183. Rather than being a useful, permissible shortcut, API submits that the currently contemplated approach will be wasteful of time and resources¹³.

¹³ Costs are mentioned, “multiple iterative rulemakings to develop needed test data would be prohibitively costly to EPA,” 61 Fed. Reg. at 33183, but they are neither explained , established nor quantified.

Promulgating and implementing the broad rule EPA has proposed will necessarily commit a substantial amount of the Agency's scarce resources. For instance, it will need to address the myriad technical and administrative issues that will go along with such a broad testing rule and will be faced with large amounts of data to receive, process, and review. Whatever time may be "saved" by this overbroad testing may be "lost" as a consequence of the Agency's required analysis of voluminous, only marginally relevant data. An iterative approach does not necessarily mean that there will be many rulemakings. Initial testing might generate sufficient data for residual risk assessments, thereby obviating the need for further testing. Even if there were additional rulemakings under an iterative approach, each would allow for constructive discussion and the targeting of testing requirements. Thus, a step-wise approach (as suggested by NAS) may well result in quicker, more responsive and better focused data necessary to support timely regulatory action under CAA section 112. While EPA may be facing certain CAA deadlines, none of these deadlines directly or indirectly demand that EPA reject a far more reasonable and appropriate approach to data collection.

API favors a phased approach for this and future test rules. We believe this approach to be superior because it is more cost-effective, focuses scarce resources on collection of data that is actually needed for purposes of risk assessment, and minimizes the possibility of unnecessary animal testing.

B. EPA's emphasis on "an even, across-the-board database" is not justifiable for this diverse set of compounds.

The proposed test rule covers a set of 21 compounds that are extremely diverse. They vary considerably in physical and chemical properties, exposure profiles, amount and pattern of emissions, known or suspected toxicity, and availability of health effects data. EPA's supporting documents for the proposed rule document this diversity among the chemicals.

In formulating testing requirements for HAPs, EPA should focus on the data gaps that most need to be filled for the purposes of residual risk assessment mandated by the CAA. This would involve formulating appropriate requirements on a chemical-by-chemical basis rather than proposing “across-the-board” testing to address a broad set of endpoints. For example, less testing may be necessary to perform adequate risk assessments for those HAPs for which exposures will be very low (e.g. HAPs for which there are very few major sources or for which air dispersion modeling demonstrates very low fence-line concentrations).

C. EPA's screening approach is inappropriate.

EPA explains that it selected HAPs for consideration for testing by focusing its attention on HAPs with 1993 TRI emissions of 50 tons (100,000 pounds) or more. 61 Fed. Reg. at 33184. This approach is flawed for the following reasons.

First, the choice of the 50-ton limit is low and not adequately justified. EPA's own policy for making TSCA section 4(a)(1)(B) findings defines “substantial release” as annual release into the environment of 1 million pounds or 10 percent of production.

Second, MACT regulations are being implemented to reduce HAP air emissions, the focal point of this rulemaking. For example, EPA has estimated that the MACT standard for petroleum refineries will reduce HAPs emissions from these facilities by 59 percent. 60 Fed. Reg. 43244-6 (Aug. 18, 1995). EPA has developed and is developing estimates of reduced HAP emissions to support MACT rulemakings. This information should form the basis for targeting where residual risks may exist under CAA section 112, yet EPA has not considered this work here. In view of the evolving implementation of MACT standards, it would appear that any screening number (e.g., 50 tons) should apply to anticipated, post-MACT emissions, not to past emissions that have not yet been subject to those controls. If the Agency is to use a retrospective approach and rely on TRI data, it should screen those releases against the Agency's current guideline of 1 million pounds.

Third, EPA's use of 1993 TRI data is inappropriate; more recent TRI data are available.

Fourth, EPA does not appear to have done any evaluation of the nature or pattern of air releases nor to have evaluated potential for significant general population exposure to the releases.

Fifth, EPA cites the Clean Air Act definition of “major source” to justify its 50-ton screening criterion, but it does not take into account the fact that some of the selected compounds have very few major sources of emissions. Given that a “major source” is defined as emitting 10 tons per year or more of any HAP or 25 tons per year or more of any combination of HAPs, the screen EPA has devised would screen out very few HAPs. Indeed, just a handful of major sources barely meeting the 10 ton per year definition would trigger the screen.

The flaws in EPA's screening methodology are particularly important when the primary purpose of this testing --- residual risk assessment for use in the post-MACT program—is kept in mind. EPA has, in effect, used a very broad and arguably skewed screen for its selection of chemicals to be tested and then, in turn, proposed a very broad set of testing requirements. The overall effect is a proposed rule that goes well beyond that which is reasonably necessary for residual risk assessments under the MACT program.

VI. PROPOSED TESTING

As noted previously, this proposed test rule does not apply to refineries. However, API would like to provide comments on several generic toxicological issues raised by EPA's proposed rule. These include:

- 1) the suggested use of immunotoxicity testing, is premature and that using it only as a screen does not avoid its inherent shortcomings;
- 2) low vapor pressure chemicals present special challenges;
- 3) unnecessary acute toxicity testing is specified; and
- 4) the Agency's grudging acceptance of route-to-route extrapolation and the preconditions it imposes will likely result in good data being ignored.

An added, generic shortcoming arises out of the proposal's overly optimistic assumption that adequate contract laboratory capacity exists. As EPA and the states require more testing under the CAA and other statutes/programs, it is inevitable that delays will result from a lack of available laboratory capacity. Each of these issues will be discussed separately below.

A. Immunotoxicity testing (even as a screening tool) is premature.

This is the first time immunotoxicity testing has been specified in a test rule. In fact, the Agency only recently proposed health effect guidelines for immunotoxicity testing (OPPTS Health Effects Test Guideline 870.7800). The Agency notes that immunotoxicity testing is a new field and that the application of immunotoxicity data to risk assessment is not yet sufficiently matured and has not been incorporated into risk assessment paradigms. As the primary purpose of this rule is to collect data for use in residual risk assessments, this calls into question EPA's need for these data. If, as EPA indicates, these data are a screen, then the use of these data for risk assessment purposes is even more limited; uses and need should be clearly established *before* collecting any data under this or other TSCA test rules.

It is also perplexing that the Agency refers to the 870.7800 guideline as a "screen" for immunotoxicity. The guideline lists specific tests that are sensitive indicators of chemically induced suppression of the immune system. Attempts to interpret results derived from these

assays for effects other than immunosuppression would be inappropriate. Further, EPA's reference to the use of this health effects testing guideline as a screen suggests that additional testing will be required, but no other testing is listed for immunotoxicity.

Given that the primary purpose of this rule is to collect data for use in residual risk assessment, API believes that requiring immunotoxicity screening is premature. Rather than requiring immunotoxicity testing in anticipation of a future risk assessment methodology, EPA should wait until risk assessment methodology for immunotoxicity is complete (or at least more mature), and then collect data as necessary. The proposed "standby" collection of immunotoxicity data is poor policy that could result in an inefficient and/or misdirected expenditure of resources. Furthermore, because science and policy regarding immunotoxicity information is at such an early stage, the data collected under this test rule could be easily misinterpreted or misused.

As to specific concerns with this testing and the Agency's previously proposed testing guidelines, EPA notes that the immunotoxicity testing should be conducted in conjunction with subchronic or reproductive exposures. However, for those several HAPs for which immunotoxicity testing is required, neither subchronic nor reproductive toxicity testing is required. The Agency also needs to delineate an appropriate dosing regimen for these materials. The 870.7800 guideline recommends at least 30 days exposure by oral or parenteral administration; inhalation exposures are not addressed. EPA states in the HAPs proposal that oral data can be used, but only with pharmacokinetic data (preferably a PBPK model). For chemicals which have no requirement for subchronic or reproductive testing, the Agency needs to state whether oral exposure will be acceptable or if separate inhalation exposures will be required.

In regard to the specific assays required in the 870.7800 guideline, API does not support the use of enumeration of splenic or peripheral blood T and B cells. This assay is very time and labor intensive. The assay requires the procurement of a specific analytical machine, a flow

cytometer, and a dedicated technician to run this machine. Historical control data exists for mice, but no historical control data has been developed for rats. Further, experience with mice indicate that there are marked strain differences in this assay. API suggests that this assay be replaced by the Natural Killer Cell Activity Assay that EPA already allows for substitution in the proposed health effects testing guideline.

B. EPA should consider alternative testing proposals for low vapor pressure compounds.

The Agency is proposing that three chemicals diethanolamine, 1,1' biphenyl, and phthalic anhydride, be tested as aerosols due to their low vapor pressure. However, the Agency seeks information to address two questions: (1) is there human exposure to vapor, aerosol or particle? and (2) what is the appropriate toxicology study to address these exposures? The Agency is soliciting input on the form of ambient exposures (i.e., vapor, aerosol, or particle) for these chemicals and the most appropriate toxicity testing depending on the form of exposure.

API supports EPA's decision to determine human ambient exposure to materials with low vapor pressure based on the actual chemical phase of the substance. API believes that the appropriate testing of these chemicals depends upon the chemical phase to which humans are exposed. If ambient exposures to a chemical are to its vapor phase, the toxicity testing should be of the vapor.¹⁴ Likewise, if chemical exposure is to an aerosol (or particle formed by the chemical), the toxicity testing should be conducted on the aerosol.

Aerosol/Particle Testing - In considering toxicity testing of aerosols, due to emission of chemical aerosol, it is also important to determine that human exposure to an aerosol actually occurs. The size of the aerosol droplet will affect the distance the aerosol can travel after release,

¹⁴ The only exception might be for acute toxicity testing of low vapor pressure chemicals used to assess potential risks from accidental release scenarios. It is plausible in these situations that aerosols can be generated and human exposure to aerosols would occur. So considered, it may be reasonable to conduct acute aerosol inhalation toxicity testing of a low vapor pressure material for which the ambient exposure would be in the vapor phase.

and the ability of the aerosol droplets to be inhaled. Further, particle size of an aerosol will affect its distribution within the respiratory system. If exposure data indicate that large droplets are formed, it is likely that this material will rain out a short distance from its release site and not be respirable due to particle size. Thus, exposure of the general public to this aerosol would be minimal, and toxicity testing of the aerosol would be inappropriate. However, if the aerosols are of appropriate size to travel beyond the fenceline and are respirable, toxicity testing could be appropriate.

For low vapor pressure chemicals to which humans are exposed to the vapor phase, API urges EPA not to require inhalation toxicity testing on the aerosols of these chemicals. It is inappropriate to extrapolate toxicity information from an aerosol study to vapor exposures of the same chemical. First, the distribution of these phases in the respiratory tract are tremendously different. Aerosols will distribute to different regions within the respiratory tract based on the size of the particle, while vapors will distribute based on water solubility of the chemical. Thus, it could be possible to alter the region in the respiratory tract with which a chemical will interact. Additionally and for a given region, aerosols will affect a few cells near where the particle lodges, as opposed to a vapor which can affect all cells. Finally, transfer of the chemical from the respiratory tract to the systemic circulation can be different between aerosols and vapors. Absorption of gases from the lung is largely dependent upon the solubility of the gas within the blood. The pathways and kinetics of absorption of aerosol particles is more varied, and depends on the site of particle deposition and solubility of the chemical. Thus, it is conceivable that an aerosol of a chemical may interact at a different site within the respiratory tract than the vapor phase of the same chemical. Further, the kinetics of interaction at the systemic target site may be altered as well due to the physical state of the chemical. Attempting to account for these differences, in hazard identification as well as dose-response modeling for risk assessment purposes may be fraught with uncertainty. Therefore, API suggests that EPA require toxicity testing on the chemical phase to which ambient exposure occurs for materials with low vapor pressure.

API urges the Agency to adopt a margin of safety analysis of low vapor pressure chemicals with ambient vapor exposures. First, API recommends a limit test for inhalation toxicology. This toxicity test would be conducted at the maximum attainable vapor concentration for the particular chemical substance. The result from this test would then be compared to measured ambient air concentrations at the facility fenceline. If the saturated vapor concentration achieved in a limit test is sufficiently higher than the fenceline concentration (approximately 100x higher), then no further toxicity testing is required. For chemicals with a less acceptable margin of safety, testing alternatives should be considered, including oral toxicity studies.

API does not concur with EPA's proposal to require new oral toxicity studies as blanket substitutions for inhalation toxicity studies on low vapor pressure HAPs. API believes that existing oral toxicity studies provide useful information to assess the risk of HAPs and should be used in a weight of the evidence examination of potential hazards from HAPs exposure. API does not agree with requiring new oral toxicity studies for the sole purpose of increasing the dose administered to produce an adverse effect. In recommending the use of new oral toxicity studies, EPA argues that using oral studies would be less expensive than inhalation studies, and the information would provide data that can be used to determine human risk (i.e., the dose would be high enough to produce an effect). API disagrees with this rationale. First, the amount of pharmacokinetic data required by the Agency in this rule to allow for route-to-route extrapolation would be as expensive to obtain as conducting inhalation exposures in a limit test. Second, the use of oral toxicity studies solely for the purpose of increasing the dose administered to produce an adverse effect is inappropriate. Oral administration of the compound would likely produce an internal dose that could not be attained by inhalation exposure due to the low vapor pressure of the chemical. Thus, the usefulness of the observed toxicity from an oral study would be questionable. It is conceivable that an RFC derived from an oral study and route-to-route extrapolation would be useless if it is over the maximum achievable vapor concentration. Further, the oral toxicity data and route-to-route extrapolation with uncertainty factors added,

could lead to a RFC which, when compared to an inhalation study of the vapor, is below the threshold for effect. As such, API believes that substitution of new oral for inhalation toxicity studies should only be used as a last resort.

C. Unnecessary acute toxicity testing.

The Agency has included acute pulmonary toxicity testing in the proposed HAPs test rule; it also recently proposed revisions to this testing guideline (870.1350). The test guideline now is a phased guideline with a 4 hour inhalation exposure with pulmonary histopathology and bronchoalveolar lavage to assess toxicity of inhaled chemicals. If toxicity is observed, 1 and 8 hour exposures are triggered to further examine the pulmonary toxicity.

The Agency argues, in both the proposed testing guideline and this rule, for a stepwise approach in terms of exposure duration. No rationale, however, is advanced for an additional eight hour exposure to examine pulmonary toxicity. The Agency does not make clear how this data will be used, and the logic for this exposure is not apparent. If a chemical produces toxicity after four hours of exposure, it is reasonable to assume that toxicity will be observed at eight hours of exposure. Generation of another data set with longer exposures will not clarify the issue. The 1 hour exposure, assuming a toxic effect is observed at 4 hours of exposure, could be useful in accidental release scenarios, but even then the Agency should take a chemical specific approach. Only those materials for which there is reasonable concern for accidental release *and* a potential exposure to the general population should be subject to 1 hour testing.

D. Unnecessary restrictions are imposed on the use of route-to-route extrapolation.

The Agency will allow the use of route-to-route extrapolation so that oral toxicology studies could be used in lieu of additional inhalation toxicology testing. API generally supports this position but disagrees with the Agency on the amount of pharmacokinetic data required to conduct these extrapolations (in lieu of additional toxicology testing).

The Agency prefers the development of physiologically-based pharmacokinetic (PBPK) models in order to conduct route-to-route extrapolations. The Agency desires a model that describes disposition of the chemical and includes biological parameters such as blood flows, ventilatory parameters, metabolic capacities, and renal clearance for each chemical. Additionally, these models are to be used with mechanistic and toxicity information. EPA recognizes that the accumulation of all this data can be very time consuming task; we agree and submit that it is overly burdensome. Few chemicals have had PBPK models developed to the rigor EPA seeks. Indeed, for chemicals such as 1,3-butadiene, several PBPK models exist, some of which predict markedly different results. The amount of data needed to generate these models is overwhelming. By calling for this type of model to be developed, it appears that EPA is putting an obstacle in place of the use of good science and reasonable extrapolation.

The Agency appears to suggest that pharmacokinetic data short of a PBPK model will be acceptable to conduct route to route extrapolations, but it cautions that such data will be treated with “a consideration of the uncertainties involved” in the use of these data. 61 Fed. Reg. at 33189. PBPK models have been developed to reduce the uncertainties in extrapolation of toxicology data across animal species; it now appears that the Agency is placing more uncertainty with the use of pharmacokinetic data within a species. The Agency should more clearly indicate what uncertainties are to be considered when using pharmacokinetic data short of a full PBPK model.

E. The availability of laboratory capacity must be considered when establishing compliance deadlines

This proposal identifies 95 separate toxicology endpoints for 23 chemicals (including 3 isomers of cresols) requiring approximately 70 separate inhalation studies. The specific testing for each chemical varies, but generally consists of short term exposures for acute and developmental endpoints and longer term exposures for subchronic, reproductive and carcinogenic endpoints. In total, there are 23 acute toxicology exposures (one day, 4 hour), 10 subchronic exposures (at least 13 weeks), 11 developmental exposures (at least 3 weeks), 12 reproductive exposures (at least 32 weeks), 4 carcinogenicity exposures (104 week), and eight exposures where neurotoxicity or immunotoxicity tests are not linked to subchronic exposure. All acute testing to be completed in 21 months, all subchronic testing in 18 months, all developmental toxicity testing in 12 months, all reproductive testing in 29 months and all carcinogenicity testing in 60 months.

The Agency's proposed compliance deadlines are similar to those required to test an individual chemical. When only one chemical is considered, laboratory capacity is unlikely to be an acute compliance problem (unless uniquely extensive testing is required and/or an entirely new test is specified and only a few qualified laboratories are available). Here, not only are numerous chemicals involved (21), but extensive testing is required and innovative approaches to testing suggested (immunotoxicity). Given the inhalation toxicology laboratory capacity currently available, it is unlikely that the proposed compliance schedule could be met¹⁵.

¹⁵ This circumstance may be exacerbated further because several of the proposed tests require that other tests precede them (e.g., subchronic testing should be completed prior to carcinogenicity testing).

Mandated and proposed testing from other EPA rules¹⁶ having an impact on available laboratory capacity must be considered before setting testing deadlines here or under any new or pending test rules. The Act expressly requires EPA to consider “the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule.”

TSCA section 4(b)(1). Since total laboratory demand unquestionably affects the “reasonably foreseeable availability” of laboratories, EPA is required to consider not just the testing required under this rule, but also testing required elsewhere and testing performed as an adjunct to sound product safety stewardship programs¹⁷. Taking into account this total demand, a more generic timetable should be developed that establishes phases for the completion of various studies. A possible schedule might be: all acute toxicology testing and studies (immunotoxicology and neurotoxicology tests) associated with acute toxicology exposures be completed within two years; all developmental toxicity testing be completed within three years; all reproductive and subchronic toxicity testing be completed within five years; and all carcinogenicity testing be completed within eight years.

¹⁶ For example, the petroleum industry is currently awaiting a decision by the Agency regarding an alternative tier 2 testing program for the fuel/fuel additives registration regulations under the Clean Air Act. This alternative testing program may require extensive toxicology testing on at least six fuel and oxygenated fuel blends. Although the agency has not formally delineated the alternative toxicology testing program, it has proposed at least 15 toxicology tests (13 of which require at least 3 months inhalation exposure) to examine subchronic, developmental, reproductive, and neurological toxicity of gasoline and gasoline oxygenate blends. These tests will most likely have three year limit for non cancer exposures and five year limit for carcinogenicity. The 211(b) Research Group, a testing consortium established to meet the requirements of 211(b), estimates that the testing for evaporative emission of fuel and fuel additives only will occupy at least two inhalation toxicology contract laboratories for 4 years. If exhaust emission toxicology testing is required, at least one other contract laboratory will likely be occupied with the exhaust emission toxicology testing. These requirements and routine product stewardship testing, as well as compliance with other test rules, can be expected to place a tremendous strain on and demand for available inhalation toxicology testing capacity.

¹⁷ Several of the EPA guideline studies proposed have recently been changed. These changes will need to be incorporated into laboratory standard operating procedures, thereby further delaying the initiation of required testing under this rule.

VII. PROPOSED TESTING REGIME FOR CRESOLS, NAPHTHALENE AND ETHYLBENZENE

Although this proposal does not apply to refineries, API would like to comment on specific testing proposed for several HAPs. These comments are provided to assist the agency in their evaluation of existing data on these chemicals.

A. Cresols

EPA is requiring subchronic inhalation toxicity testing on each of the three isomers of cresol (ortho, meta, and para). Several subchronic toxicity studies on cresols have already been conducted. As noted in the Agency's supporting documentation the National Toxicology Program (NTP) has already conducted 28-day and 13-week studies on all three cresol isomers in both F344 rats and B6C3F1 mice. The only shortcoming of the NTP studies for EPA's purposes under the HAPs program would appear to be that the NTP studies were done using an oral route of exposure. The EPA's HAPs support document states that, "The NTP study was by the oral route and while it showed some effects on the nasal epithelium, acute and subchronic inhalation studies are necessary to characterize portal of entry effects."

The EPA's rationale to have subchronic inhalation toxicity studies conducted on cresol isomers to characterize portal of entry effects does not seem well reasoned. API believes that information sufficient to characterize portal of entry effects (presumably irritant in nature) will be gained from the cresol studies on acute inhalation toxicity and respiratory sensory irritation. Evidence that these sites are adversely affected by cresol exposure is already evident from the subchronic oral studies. The nasal epithelium was irritated following dietary exposure to cresols. This effect could be produced via a systemic exposure of the nasal epithelium (i.e., cresols ingested in the diet, absorbed in the general circulation, distributed to the nasal epithelium to produce adverse effects). It is more likely, however, that cresols mixed directly in a powered diet may cause direct irritation of the nasal epithelium as the rat feeds. This type of entry

approximates that which would be observed by inhalation studies and bolsters the argument that an acute inhalation study is sufficient to identify portal of entry effects. If cresols are irritating to the nasal epithelium from a systemic exposure (i.e., cresols ingested in the diet, absorbed to the general circulation, distributed to the nasal epithelium to produce adverse effects), then confirmation of this finding from an acute inhalation exposure is all that is needed. If the nasal epithelium is adversely affected in an acute inhalation exposure, it can be assumed in a subchronic study, that delivery of cresols directly to the nasal epithelium will be sufficient to produce an adverse effect.

API believes that additional subchronic toxicology testing is unnecessary. Inferences about systemic target organ toxicity can be made by using information from the NTP oral studies. The doses in these studies were sufficiently high to produce adverse systemic effects. Concentrations of cresol as high as 30,000 ppm in the diet were utilized. This dose yielded an average intake of approximately 2 gm cresols/kg/day in the rat 13-week study. For mice, the high dose was 20,000 ppm in the diet, and this also yielded average doses ranging from approximately 1.5 to over 3 gm/kg/day depending on the particular cresol isomer and sex of mouse. These doses actually exceed the Agency's recommended limit dose of 1 gm/kg/day for subchronic oral studies and therefore provide a more than adequate dosing regimen for evaluation of potential systemic effects of cresols. The results of these studies should be utilized for the HAPs residual risk program by making reasonable assumptions about route-to-route extrapolation and delivered tissue doses of cresols.

According to EPA's Support Document, the NTP is planning to conduct a two-year chronic feeding study on all three cresol isomers. If this is in fact the case, this study will provide additional data for evaluating the health effects of cresols. The information provided could be used to evaluate the systemic effects of cresol isomers based on a long term exposure and provide additional confidence on the results of ninety day exposures. Thus, the need for subchronic inhalation studies on cresols would appear to be dubious, at best.

There is additional consideration weighing against the utility of conducting a subchronic inhalation study which API would like to bring to the attention of EPA. This consideration relates to the physical forms of the ortho meta and para isomers of cresol. Both the ortho and para cresol isomers are solids at room temperature. The physical state of these isomers makes generation of an atmosphere for inhalation exposure extremely difficult. The exposure atmosphere would most likely have to be an aerosol, and this exposure would raise questions on the relevance of the use of the data (see above comments on toxicology testing for compounds with low vapor pressure). Although this data may be used for assessment of acute health effects from an accidental release scenario, the extrapolation of a subchronic exposure of an aerosol to potential health effects of a low level continuous vapor exposure is dubious. This fact calls into question the practicality as well as the utility of conducting additional subchronic studies on the ortho and para isomers.

In summary API believes there is scant justification for requiring subchronic inhalation studies on cresols. Data already available from the NTP studies should be sufficient to allow EPA to make reasoned decisions regarding the potential subchronic toxicity of these compounds.

B. Naphthalene

EPA proposes toxicology testing for naphthalene to examine acute toxicity, reproductive toxicity, immunotoxicity and respiratory sensory irritation. The inhalation route of exposure appears to be the major concern since most available data is from studies where naphthalene was administered orally. EPA chooses not to use these studies as they were not conducted by inhalation exposures.

EPA considers the available acute inhalation toxicity data on naphthalene inadequate based on the absence of histopathology and an inadequate range of endpoints. The study cited by EPA reported no deaths and no gross pathology at a four hour exposure level 7- fold higher than the current TLV of 10 ppm approved by ACGIH in 1996. Clinical signs observed in this study

were consistent with sensory irritation. Moreover, Warren et al. (1982) and O'Brien et al. (1985) have demonstrated that acute exposure to naphthalene in rats and mice can result in damage to pulmonary bronchiolar epithelial cells. These studies should be used to assess acute respiratory toxicity. Further, the subchronic inhalation studies proposed or already in progress should delineate any significant toxicity of naphthalene in the lung. In the interest of conserving resources additional acute inhalation testing with pathology should be deferred until lung toxicity, if any, is demonstrated in longer term studies, indicating a need for more investigation of acute exposure hazard to the lung.

API believes that adequate information exists to assess the potential immunotoxic effects of naphthalene. Individually, these studies discussed below do not meet the specific requirements outlined in 870.7800. However, taken together as a whole they support the conclusion that naphthalene is not immunotoxic. EPA does not consider the studies of Shopp et al. (1984) in mice exposed to naphthalene by gavage for 14 days (267 mg/kg/day) or 90 days (133 mg/kg/day) adequate to demonstrate the absence of immunotoxicity from naphthalene. Immunotoxicity was assessed in this study by examination of humoral immune response, response to mitogens, delayed hypersensitivity response and popliteal lymph node response, bone marrow stem cell response and DNA synthesis. The authors concluded no immunotoxicity was observed. Further confirmation of no immunotoxic response is provided by studies by Kawabata and White (1990) on the effect of naphthalene and metabolites on the antibody forming cells response of splenic cell cultures to sheep red blood cells. This study also did not demonstrate an immunosuppressive effect by naphthalene. Further, these data advance the concept that the absence of immunosuppression reported by Shopp et al. may be related to the inability of splenocytes to metabolize naphthalene and that the concentration of naphthalene metabolite generated in the liver that diffuses to the spleen may be inadequate to produce immunotoxicity. Additionally, a recent in vivo study by Silkworth et al. (1995) which screened the ability of 15 PAHs separately to suppress antibody response in C57Bl/6 (Ah^{+/+}) mice

immunized after a single oral dose also demonstrated that naphthalene had little or no immunosuppressive effect. Taken as a whole, these studies indicate that naphthalene is not an immunotoxic agent and thus additional immunotoxicity testing is not warranted.

C. Ethylbenzene

EPA concludes that “testing of ethylbenzene is necessary to develop data for acute toxicity, developmental toxicity, reproductive toxicity, neurotoxicity, immunotoxicity, and respiratory sensory irritation.” API disagrees with this conclusion in particular with the need for immunotoxicity and developmental toxicity studies.

The foundation for EPA’s request for immunotoxicity data is not apparent. NTP examined the subchronic and chronic inhalation toxicity of ethylbenzene in mice and rats. These studies did not observe any adverse effects in immune organs (thymus, spleen, and lymph nodes). There have been no reports suggesting that ethylbenzene is immunotoxic. Thus, there appears to be no justification for conducting these studies other than to check a box on a matrix of endpoints to be examined.

API believes there is sufficient data available to evaluate developmental toxicity. The report by Andrew, et al. (1981) provides extensive data on rats and rabbits but is disqualified by EPA because the highest dose tested (1000 ppm) was not maternally toxic in rabbits. This seems to be a minor criticism for a report that does provide pertinent data on developmental toxicity. Further, the Ungvary and Tatrai studies, cited by EPA as being minimally adequate, provide no information on maternal toxicity. (EPA may prefer these studies over the study of Andrew et al., because adverse effects were reported following continuous exposure to ethylbenzene.) Additionally, a study in rats by Hardin, et al. (1981) (Hardin, B.D., Bond, G.P., Sikov, M.R., Andrew, F.D., Beliles, R.P., and Niemeier, R.W. (1981) "Testing of Selected Workplace Chemicals for Teratogenic Potential. Scandinavian Journal of Work Environment and Health, 7

(supp. 4), pp. 66-75.) is not cited by EPA. This study found minimal teratogenic effects for ethylbenzene. Thus, it would appear that there is adequate information from which to evaluate potential developmental toxicity from ethylbenzene exposure.

VIII. USES FOR TEST DATA

API is concerned about the public policy implications of statements regarding the use of test data “to better inform communities and citizens of toxic chemical hazards in their own localities.” 61 Fed. Reg. at 33180. API believes that EPA should concentrate on improving its risk assessment and communication methods so as to provide information to the public in a meaningful and responsible fashion. API recognizes that improving knowledge of the health effects of chemicals is a critical component of better risk assessment and communication, but the collection of large amounts of test data on the specified HAPs on the grounds that it will contribute to “a comprehensive right-to-know program” may be misguided. Better right-to-know policy would focus on responsible assessment, rather than communication of such highly technical information.

API believes that the critical goal of right-to-know programs should be to accurately and effectively assess, characterize, and communicate risk. EPA policy provides that risk assessments should contain risk characterizations that synthesize information, provide perspective on the weight to be placed on various studies, and highlight what conclusions can (and cannot) be drawn from the information at hand. The information to be collected under this proposal is highly technical data that is several steps removed from comprehensible risk assessment and risk characterization. EPA's right-to-know policy should move away from simply presenting the public with large amounts of unsynthesized data (a/k/a “data dump”) and towards providing more meaningful information about risks and their significance.

IX. CONCLUSION

EPA's proposed test rule would require a significant commitment of time and resources by the government and the regulated community and may be a precedent for future test rules. API remains committed to working with EPA in the hope that our efforts and those of other affected members of the regulated community will sensitize the Agency to our legitimate concerns so that better, more well informed policies are identified and reasonable rulemakings result. EPA's final rule should reaffirm prior precedent established by EPA under sections 4, 8a, 8b and 8d of TSCA, i.e., only petroleum refiners who isolate constituents of petroleum streams for commercial sale, are subject to TSCA section 4 test rules.